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Subject: DAILY ENV REPORT 4/11 -IRIS
Date: 04/11/2011 09:29 AM

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Risk Assessment

Academies Panel Finds EPA Fails to Support Key Conclusions on Formaldehyde, Leukemia

A National Academies panel April 8 urged the Environmental Protection Agency to substantially revise a draft assessment on formaldehyde to more adequately support key conclusions, such as its finding that the chemical causes leukemia and other cancers.

The agency is supposed to follow numerous guidance documents before it concludes a chemical causes specific health effects, said Jonathan Samet, chairman of the National Research Council's Committee to Review EPA's Draft IRIS [Integrated Risk Information System] Assessment of Formaldehyde.

IRIS assessments are the agency's consensus conclusions about the human health hazards of a chemical and the doses at which the compound may cause harm. Risk assessors combine that information with exposure data to estimate risks various specific exposure scenarios pose.

The draft assessment of formaldehyde failed to meet EPA's own standards of evidence, meaning it failed to make the case that formaldehyde harms the neurological system, causes reproductive and developmental toxicity, and produces leukemia and lymphoma, Samet told BNA.

EPA may be able to make that case, but the draft assessment the panel reviewed did not, he said. The agency reached its conclusions on cancers by focusing on research the National Cancer Institute conducted on workers.

The National Academies panel report said EPA's 1,000-page analysis needs "rigorous editing" to reduce the volume of the text substantially and to address redundancies and inconsistencies.

EPA failed to explain its rationale for reaching conclusions about the health hazards of formaldehyde and failed to consistently examine the strengths and weaknesses of critical studies, the report found.

In its report, the committee said it does not want the agency to provide long written descriptions in a revised assessment, but "rather clear concise statements of criteria used to exclude, include, and advance studies."

In an April 8 response to the committee's report, the agency said: "EPA conducts peer review to assure only the highest quality science is used as the basis of our actions. We will carefully and expeditiously review the report, as we do with all peer review reports, and examine how best to respond to its recommendations. Strong science depends on peer review and the robust discussions among scientists represents a strong scientific process."

Divergent Interpretations of Report

The American Chemistry Council, which represents major chemical manufacturers, and the Natural Resources Defense Council drew different conclusions from the National Research Council committee's review of the draft IRIS assessment.

Joseph V. Rodricks, a consultant with Environ who briefed the American Chemistry Council about the National Research Council's report, acknowledged that the panel did not say "EPA got it wrong" by concluding formaldehyde causes leukemia and lymphoma.

Instead, the panel told EPA to better support its conclusion, he said.

Rodricks said he interprets the evidence on leukemias as "virtually nonexistent." The panel's report, however, says EPA must address the topic and hence urges EPA to do so clearly and consistently, he said. Rodricks's argument has long been made by chemical manufacturers ([109 DEN A-5, 6/9/10](#)).

David Fischer, an American Chemistry Council attorney, said there is an important nuance at issue. The academies' panel could not say EPA was wrong because that would suggest the panel had done its own evaluation of the scientific evidence on formaldehydes' health hazards, which it did not.

The academies panel did, however, say EPA has not proved formaldehyde causes leukemias and a variety of other health problems, Fischer said.

Jennifer Sass, a senior NRDC scientist, interpreted the academies' advice differently.

"The academies recommended that EPA rewrite its report to more clearly communicate the scientific reasoning underpinning its assessment," she told BNA and later wrote in a blog.

“While asking EPA to state its reasoning more concisely, the academies supported development of a cancer risk estimate for leukemia,” she said.

Broader Recommendations

Samet, Rodricks, and Sass agreed on broader points made by the academies' report.

The report strongly urged EPA to improve future IRIS assessments by using consistent approaches to clearly document the reasons behind any conclusions it reaches.

“The committee is concerned about the persistence of problems encountered with IRIS assessments over the years, especially given the multiple groups that have highlighted them, and encourages EPA to address the problems,” the report said.

It may take time, but “this task is not insurmountable,” the panel said.

By [Pat Rizzuto](#)

The report of the National Research Council's Committee to Review EPA's Draft IRIS Assessment of Formaldehyde is available at http://www.nap.edu/catalog.php?record_id=13142.

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ISSN 1521-9402

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